

Substitute Specification – Clean Version

WHAT IS CLAIMED IS:

1. An electrochemical sensor for detecting the concentration of an analyte in a fluid test sample, the sensor comprising:

a flow path for receiving the fluid test sample;

5 a first lead and a second lead each adapted to be electrically coupled with a detector of electrical current;

a working electrode disposed along the flow path, the working electrode being in electrical communication with the first lead;

10 a counter electrode in electrical communication with the second lead, the counter electrode having a low-resistance portion and a high-resistance portion, the low-resistance portion of the counter electrode being disposed along the flow path downstream from the working electrode, the high-resistance portion of the counter electrode being disposed along the flow path upstream from the working electrode;

15 a resistor electrically coupled between the high-resistance portion of the counter electrode and the second lead; and

a reagent disposed on the working electrode, the reagent being adapted to react with the analyte to produce electrons that are transferred to the working electrode;

20 wherein a first current profile is produced at the first and second leads in response to a voltage profile applied to the first and second leads when electrical communication occurs between only the high-resistance portion of the counter electrode and the working electrode, a second current profile is produced at the first and second leads in response to substantially the same voltage profile applied to the first and second leads when electrical communication occurs between the low-resistance and high-resistance portions of the counter electrodes and the working
25 electrode, the first current profile being different than the second current profile.

2. The sensor of claim 1 wherein the second current profile has a decay-type shape.

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3. The sensor of claim 1 wherein the resistor has a resistance of about 50 k Ω to about 500 k Ω .

4. The sensor of claim 3 wherein the resistor has a resistance of about 250 k Ω to about 350 k Ω .

5 5. The sensor of claim 1 wherein electrical communication occurs between only the high-resistance portion of the counter electrode and the working electrode when a less than predetermined volume of fluid sample is received by the flow path.

6. The sensor of claim 1 wherein electrical communication occurs
10 between the low-resistance portion of the counter electrode and the working electrode when at least a predetermined volume of fluid sample is received by the flow path.

7. The sensor of claim 1 wherein the first current profile and the voltage profile have similar shapes when electrical communication occurs between only the high-resistance portion of the counter electrode and the working electrode.

15 8. The test sensor of claim 1 wherein the first and second leads are electrically coupled to the detector of electrical current, the detector being adapted to generate an under-filled error signal when a current profile produced at the first and second leads in response to a voltage profile applied to the first and second leads does not have a decay-type shape.

20 9. The test sensor of claim 1 wherein the reagent comprises glucose oxidase.

10. The test sensor of claim 1 further comprising a reaction layer that includes the reagent, the reaction layer covering the working electrode and the low-resistance portion of the counter electrode.

25 11. A method for evaluating whether an electrochemical test sensor is properly filled, the test sensor including a working electrode electrically coupled to a first lead and a counter electrode electrically coupled to a second lead, the counter electrode including a low-resistance portion and a high-resistance portion, the method comprising the acts of:

30 applying a voltage profile across the first and second leads;

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measuring the current profile at the first and second leads in response to the applied voltage profile; and

generating an under-filled error signal when the measured current profile does favorably compare to a predetermined profile.

5 12. The method of claim 11 wherein the predetermined profile is a decay-shaped profile.

 13. The method of claim 11 comprising forming an electrical communication between only the high-resistance portion of the counter electrode and the working electrode when the test sensor is under-filled.

10 14. The method of claim 11 comprising forming an electrical communication between the low-resistance and high-resistance portions of the counter electrode and the working electrode when the test sensor is appropriately-filled.

 15. The method of claim 11 wherein the fluid test sample comprises blood.

15 16. The method of claim 11 wherein the analyte comprises glucose.

 17. An electrochemical sensor for detecting the concentration of glucose in a blood sample, the sensor comprising:

 a flow path for receiving the blood sample;

 a first lead and a second lead each adapted to be electrically coupled with a
20 detector of electrical current;

 a working electrode disposed along the flow path, the working electrode being in electrical communication with the first lead;

 a low-resistance counter electrode disposed along the flow path downstream from the working electrode, the low-resistance counter electrode being in electrical
25 communication with the second lead;

 a high-resistance counter electrode disposed along the flow path upstream from the working electrode, the high-resistance counter electrode being in electrical communication with the second lead;

 a resistor electrically coupled between the high-resistance counter electrode
30 and the second lead; and

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a reagent disposed on the working electrode, the reagent being adapted to react with the glucose in the blood sample to produce an electrochemical reaction indicative of the concentration of the glucose in the blood sample;

5 wherein a first current profile is produced at the first and second leads in response to a voltage profile applied to the first and second leads when electrical communication occurs between only the high-resistance counter electrode and the working electrode, a second current profile is produced at the first and second leads in response to substantially the same voltage profile applied to the first and second leads when electrical communication occurs between the high-resistance and low-resistance
10 counter electrodes and the working electrode, the first current profile being different than the second current profile.

18. The sensor of claim 17 wherein the second current profile has a decay-type shape.

19. The sensor of claim 17 wherein the resistor has a resistance of about 50
15 k Ω to about 500 k Ω .

20. The sensor of claim 17 wherein electrical communication occurs between only the high-resistance counter electrode and the working electrode when a less than predetermined volume of blood sample is received by the flow path.

21. The sensor of claim 17 wherein electrical communication occurs
20 between the low-resistance counter electrode and the working electrode when at least a predetermined volume of blood sample is received by the flow path.

22. The sensor of claim 17 wherein the first current profile and the voltage profile have similar shapes when electrical communication occurs between only the high-resistance counter electrode and the working electrode.

23. The test sensor of claim 17 wherein the first and second leads are
25 electrically coupled to the detector of electrical current, the detector being adapted to generate an under-filled error signal when a current profile produced at the first and second leads in response to a voltage profile applied to the first and second leads does not have a decay-type shape.

30 24. The test sensor of claim 17 wherein the reagent comprises glucose oxidase.

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25. A method for evaluating whether an electrochemical sensor is properly filled, the test sensor including a working electrode coupled to a first lead, and counter electrode coupled to a second lead, the counter electrode including a high-resistance portion and a low-resistance portion, the test sensor including a reagent disposed on the working electrode that is adapted to react with glucose in a blood sample for producing an electrochemical reaction indicative of the concentration of the glucose in the blood sample, the method comprising the acts of:
- collecting a blood sample;
 - applying a voltage profile across the first and second leads;
 - measuring the current profile at the first and second leads in response to the applied voltage profile; and
 - generating an under-filled error signal when the measured current profile is not of a predetermined shape.
26. The method of claim 25 wherein the predetermined shape is a decay-shaped.
27. The method of claim 25 comprising forming an electrical communication between only the high-resistance portion of the counter electrode and the working electrode when the test sensor is under-filled.
28. The method of claim 25 comprising forming an electrical communication between the low-resistance portion of the counter electrode and the working electrode when the test sensor is appropriately-filled.
29. The method of claim 25 wherein the reagent comprises glucose oxidase.
30. The method of claim 25 wherein the reagent is also disposed on the low-resistance portion of the counter electrode.